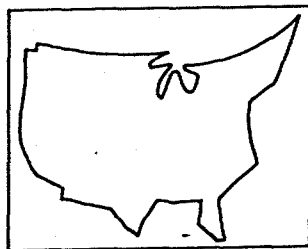


GUIDELINES



REGIONAL MEDICAL PROGRAMS

Revised MAY 1968

DISCRIMINATION PROHIBITED

Section 601 of Title VI of the Civil Rights Act of 1964, 42 USC 2000d, provides that no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. Regulations implementing the statute have been issued as Part 80 of Title 45, Code of Federal Regulations. The regional medical programs provide Federal financial assistance subject to the Civil Rights Act and the regulations.

Each grant for construction is subject to the condition that the grantee shall comply with the requirements of the Executive Order 11246, 30 F. R. 12319 and the applicable rules, regulations, and procedures as prescribed by the Secretary of Labor.

Introduction

In the 22 months since *Guidelines* was first issued, Regional Medical Programs have made substantial progress. Fifty-four Regional Medical Programs now encompass the Nation. Fifty-three of these have received planning grants, 13 have received operational grants and many more proposals for operating funds are in various stages of development. Recognizing that momentum of Regional Programs has now shifted toward development of these operational proposals, this edition of *Guidelines* has been thoroughly revised to meet the questions, issues, and problems which can be expected to emerge at this stage of program development.

The revised *Guidelines* is organized into three sections

- Chapters I and II provide an overview of the Programs. The chapter on History and Purposes traces the major elements leading to passage of the legislation authorizing establishment of Regional Medical Programs. This is followed by a statement of the Nature and Potential of the Program, including a broad description of the process of regionalization, which is based upon the cumulative and collective experience of the 54 Regional Programs.

- Chapter III and IV comprise the grants manual, detailing Grant Policies and the Preparation and Review of Applications for planning and operational proposals.

- Chapter V is a glossary compiled to define as precisely as possible those words and terms com-

monly used in connection with Regional Medical Programs.

The provisions of *Guidelines* are intended to carry out the purposes and objectives of the authorizing legislation, consistent with overall policies of the Department of Health, Education, and Welfare and sound fiscal procedures. These provisions must be interpreted in light of the basic objectives of the program, and the clear intent of the Congress to stimulate initiative and innovation at the regional level in planning and implementing Regional Programs that are fitted to the needs and resources of the region.

If the applicant believes there is a conflict between the provisions of *Guidelines* and the effective implementation of the proposed program in his region, he is encouraged to consult with the staff of the Division of Regional Medical Programs. This is a new program in an exploratory phase. It is expected that policies and procedures will evolve with time as both the applicant and the Division learn from actual planning and operational experience. As with all statements of policy and procedure, *Guidelines* attempts to strike a balance among desirable and necessary procedures. The Division encourages diversity and innovation in the development of the Regional Medical Program. But this flexibility of approach must take place within the boundaries of the legislative authority, applicable general policies, and the necessary accountability for public funds.

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Chapter I

HISTORY AND PURPOSES OF REGIONAL MEDICAL PROGRAMS

On October 6, 1965, the President signed Public Law 89-239. It authorizes the establishment and maintenance of Regional Medical Programs to assist the Nation's health resources in making available the best possible patient care for heart disease, cancer, stroke and related diseases. This legislation, which will be referred to in these *Guidelines* as The Act, was shaped by the interaction of four antecedents: the historical thrust toward regionalization of health resources; the development of a national biomedical research community of unprecedented size and productivity; the changing needs of society; and finally, the particular legislative process leading to The Act itself.

The concept of regionalization as a means to meet health needs effectively and economically is not new. During the 1930's, Assistant Surgeon General Joseph W. Mountin was one of the earliest pioneers urging this approach for the delivery of health services. The national Committee on the Costs of Medical Care also focused attention in 1932 on the potential benefits of regionalization. In that same year, the Bingham Associates Fund initiated the first comprehensive regional effort to improve patient care in the United States. This program linked the hospitals and programs for continuing education of physicians in the State of Maine with the university centers of Boston. Advocates of regionalization next gained national attention more than a decade later in the report of the Commission on Hospital Care and in the Hospital Survey and Construction (Hill-Burton) Act of 1946. Other proposals and attempts to introduce regionalization of health resources can be chronicled, but a strong national movement toward regionalization had to await the convergence of other factors which occurred in 1964 and 1965.

One of these factors was the creation of a national biomedical research effort unprecedented in history and unequalled anywhere else in the

world. The effect of this activity is intensified by the swiftness of its creation: at the beginning of World War II the national expenditure for medical research totaled \$45 million; by 1947 it was \$87 million; and in 1967 the total was \$2.257 billion—a 5,000 percent increase in 27 years. The most significant characteristic of this research effort is the tremendous rate it is producing new knowledge in the medical sciences, an outpouring which only recently began and which shows no signs of decline. As a result, changes in health care have been dramatic. Today, there are cures where none existed before, a number of diseases have all but disappeared with the application of new vaccines, and patient care generally is far more effective than even a decade ago. It has become apparent in the last few years, however, (despite substantial achievements), that new and better means must also be found to convey the ever-increasing volume of research results to the practicing physician and to meet growing complexities in medical and hospital care, including specialization, increasingly intricate and expensive types of diagnosis and treatment, and the distribution of scarce manpower, facilities, and other resources. The degree of urgency attached to the need to cope with these issues is heightened by an increasing public demand that the latest and best health care be made available to everyone. This public demand, in turn, is largely an expression of expectations aroused by awareness of the results and promise of biomedical research.

In a sense, the national commitment to biomedical investigation is one manifestation of the third factor which contributed to the creation of Regional Medical Programs: the changing needs of society—in this case, health needs. The decisions by various private and public institutions to support biomedical research were responses to this societal need perceived and interpreted by these institutions. In addition to the support of research,

the same interpretive process led the Federal Government to develop a broad range of other programs to improve the quality and availability of health care in the Nation. The Hill-Burton Program which began with the passage of the previously-mentioned Hospital Survey and Construction Act of 1946, together with the National Mental Health Act of 1946, was the first in a series of post-World War II legislative actions having major impact on health affairs. When the 89th Congress adjourned in 1966, 25 health-related bills had been enacted into law. Among these were Medicare and Medicaid to pay for hospital and physician services for the Nation's aged and poor; the Comprehensive Health Planning Act to provide funds to each state for non-categorical health planning and to support services rendered through state and other health activities; and Public Law 89-239 authorizing Regional Medical Programs.

The report of the President's Commission on Heart Disease, Cancer, and Stroke, issued in December 1964, focused attention on societal needs and led directly to introduction of the legislation authorizing Regional Medical Programs. Many of the Commission's recommendations were significantly altered by the Congress in the legislative process, but The Act was clearly passed to meet needs and problems identified and given national recognition in the Commission's report and in the Congressional hearings preceding passage of The Act. Some of these needs and problems were expressed as follows:

- A program is needed to focus the Nation's health resources for research, teaching and patient care on heart disease, cancer, stroke and related diseases, because together they cause 70 percent of the deaths in the United States.

- A significant number of Americans with these diseases die or are disabled because the benefits of present knowledge in the medical sciences are not uniformly available throughout the country.

- There is not enough trained manpower to meet the health needs of the American people within the present system for the delivery of health services.

- Pressures threatening the Nation's health resources are building because demands for health services are rapidly increasing at a time when increasing costs are posing obstacles for many who require these preventive, diagnostic, therapeutic and rehabilitative services.

- A creative partnership must be forged among the Nation's medical scientists, practicing physicians, and all of the Nation's other health resources so that new knowledge can be translated more rapidly into better patient care. This partnership should make it possible for every community's practicing physicians to share in the diagnostic, therapeutic and consultative resources of major medical institutions. They should similarly be provided the opportunity to participate in the academic environment of research, teaching and patient care which stimulates and supports medical practice of the highest quality.

- Institutions with high quality research programs in heart disease, cancer, stroke, and related diseases are too few, given the magnitude of the problems, and are not uniformly distributed throughout the country.

- There is a need to educate the public regarding health affairs. Education in many cases will permit people to extend their own lives by changing personal habits to prevent heart disease, cancer, stroke and related diseases. Such education will enable individuals to recognize the need for diagnostic, therapeutic or rehabilitative services, and to know where to find these services, and it will motivate them to seek such services when needed.

During the Congressional hearings on this bill, representatives of major groups and institutions with an interest in the American health system were heard, particularly spokesmen for practicing physicians and community hospitals of the Nation. The Act which emerged turned away from the idea of a detailed Federal blueprint for action. Specifically, the network of "regional centers" recommended earlier by the President's Commission was replaced by a concept of "regional cooperative arrangements" among existing health resources. The Act establishes a system of grants to enable representatives of health resources to exercise initiative to identify and meet local needs within the area of the categorical diseases through a broadly defined process. Recognition of geographical and societal diversities within the United States was the main reason for this approach, and spokesmen for the Nation's health resources who testified during the hearings strengthened the case for local initiative. Thus the degree to which the various Regional Medical Programs meet the objectives of the Act will provide a measure of how well local health resources can take the initiative and work

together to improve patient care for heart disease, cancer, stroke and related diseases at the local level.

The Act is intended to provide the means for conveying to the medical institutions and professions of the Nation the latest advances in medical science for diagnosis, treatment, and rehabilitation of patients afflicted with heart disease, cancer, stroke, or related diseases—and to prevent these diseases. The grants authorized by The Act are to encourage and assist in the establishment of regional cooperative arrangements among medical schools, research institutions, hospitals, and other medical institutions and agencies to achieve these ends by research, education, and demonstrations of patient care. Through these means, the programs authorized by The Act are also intended to improve generally the health manpower and facilities of the Nation.

In the two years since the President signed The Act, broadly representative groups have organized themselves to conduct Regional Medical Programs in more than 50 Regions which they themselves have defined. These Regions encompass the Nation's population. They have been formed by the organizing groups using functional as well as geographic criteria. These Regions include combinations of entire states (e.g. the Washington-Alaska Region), portions of several states (e.g. the Intermountain Region includes Utah and sections of Colorado, Idaho, Montana, Nevada and Wyoming), single states (e.g. Georgia), and portions of states around a metropolitan center (e.g. the Rochester Region which includes the city and 11 surrounding counties). Within these Regional Programs, a wide variety of organization structures have been developed, including executive and

planning committees, categorical disease task forces, and community and other types of sub-regional advisory committees.

Regions first may receive planning grants from the Division of Regional Medical Programs, and then may be awarded operational grants to fund activities planned with initial and subsequent planning grants. These operational programs are the direct means for Regional Medical Programs to accomplish their objectives. Planning moves a Region toward operational activity and is a continuing means for assuring the relevancy and appropriateness of operational activity. It is the effects of the operational activities, however, which will produce results by which Regional Medical Programs will be judged.

On November 9, 1967, the President sent the Congress the *Report on Regional Medical Programs* prepared by the Surgeon General of the Public Health Service, and submitted to the President through the Secretary of Health, Education, and Welfare, in compliance with the Act. The *Report* details the progress of Regional Medical Programs and recommends continuation of the Programs beyond the June 30, 1968, limit set forth in The Act. The President's letter transmitting the *Report* to the Congress was at once encouraging and exhortative when it said, in part: "Because the law and the idea behind it are new, and the problem is so vast, the program is just emerging from the planning state. But this report gives encouraging evidence of progress—and it promises great advances in speeding research knowledge to the patient's bedside." Thus in the final seven words of the President's message, the objective of Regional Medical Programs is clearly emphasized.

Chapter II

THE NATURE AND POTENTIAL OF REGIONAL MEDICAL PROGRAMS

Goal—Improved Patient Care

Chapter I places the Goal of Regional Medical Programs in its historical context and gives a fuller perspective to Section 900 of the Act (see Appendix I), which defines the Goal in detail. In abbreviated form, the Goal is described in the Surgeon General's *Report* as "... clear and unequivocal. The focus is on the patient. The object is to influence the present arrangements for health services in a manner that will permit the best in modern medical care for heart disease, cancer, stroke, and related diseases to be available to all."

Means—The Process of Regionalization

Note: Regionalization can connote more than a regional cooperative arrangement, but for the purpose of *Guidelines*, the two terms will be used interchangeably. The Act uses "regional cooperative arrangement," but "regionalization" has become a more convenient synonym.

A regional cooperative arrangement among the full array of available health resources is a necessary step in bringing the benefits of scientific advances in medicine to people wherever they live in a Region they themselves have defined. It enables patients to benefit from the inevitable specialization and division of labor which accompany the expansion of medical knowledge because it provides a system of working relationships among health personnel and the institutions and organizations in which they work. This requires a commitment of individual and institutional spirit and resources which must be worked out by each Re-

gional Medical Program. It is facilitated by voluntary agreements to serve, systematically, the needs of the public as regards the categorical diseases on a regional rather than some more narrow basis.

Regionalization, or a regional cooperative arrangement, within the context of Regional Medical Programs has several other important facets:

- It is both functional and geographic in character. Functionally, regionalization is the mechanism for linking patient care with health research and education within the entire region to provide a mutually beneficial interaction. This interaction should occur within the operational activities as well as in the total program. The geographic boundaries of a region serve to define the population for which each regional program will be concerned and responsible. This concern and responsibility should be matched by responsiveness, which is effected by providing the population with a significant voice in the regional program's decision-making process.

- It provides a means for sharing limited health manpower and facilities to maximize the quality and quantity of care and service available to the region's population, and to do this as economically as possible. In some instances, this may require inter-regional cooperation between two or among several regional programs.

- Finally, it also constitutes a mechanism for coordinating its categorical program with other health programs in the region so that their combined effect may be increased and so that they contribute to the creation and maintenance of a sys-

tem of comprehensive health care within the entire region.¹

Because the advance of knowledge changes the nature of medical care, regionalization can best be viewed as a continuous process rather than a plan which it totally developed and then implemented. This process of regionalization, or cooperative arrangements, consists of at least the following elements: involvement, identification of needs and opportunities, assessment of resources, definition of objectives, setting of priorities, implementation, and evaluation. While these seven elements in the process will be described and discussed separately, in practice they are interrelated, continuous and often occur simultaneously.

Involvement—The involvement and commitment of individuals, organizations and institutions which will engage in the activity of a Regional Medical Program, as well as those which will be affected by this activity, must underlie a Regional Program. By involving in the steps of study and decision all those in a Region who are essential to implementation and ultimate success, better solutions may be found, the opportunity for wider acceptance of decisions is improved, and implementation of decisions is achieved more rapidly. Other attempts to organize health resources on a regional basis have experienced difficulty or have

been diverted from their objectives because there was not this voluntary involvement and commitment by the necessary individuals, institutions and organizations. The Act is quite specific to assure this necessary involvement in Regional Medical Programs: it defines, for example, the minimum composition of Regional Advisory Groups.

The Act states these Regional Advisory Groups must include "practicing physicians, medical center officials, hospital administrators, representatives from appropriate medical societies, voluntary health agencies, and representatives of other organizations, institutions, and agencies concerned with activities of the kind to be carried on under the program and members of the public familiar with the need for the services provided under the program." To ensure a maximum opportunity for success, the composition of the Regional Advisory Group also should be reflective of the total spectrum of health interests and resources of the entire Region. And it should be broadly representative of the geographic areas and all of the socioeconomic groups which will be served by the Regional Program.²

Identification of Needs and Opportunities—A Regional Medical Program must identify the needs regarding heart disease, cancer, stroke and related diseases within the entire Region. Further, these

¹It is not the intent of a Regional Medical Program grant to supplant either Federal or non-Federal sources of support for various activities related to achieving its purpose. Rather, the Regional Medical Program provides an opportunity to introduce activities which draw upon and effectively link activities already supported, or supportable in the future, through other sources. Current examples of other Federal programs that provide essential inputs into the health resources of the Region are: other activities of the National Institutes of Health, particularly the National Heart Institute, National Cancer Institute, and National Institute of Neurological Diseases and Blindness; other constituents of the Department of Health, Education, and Welfare particularly the Comprehensive Health Planning and Services Program in the Office of the Surgeon General, the Bureau of Disease Prevention and Environmental Control, the Bureau of Health Manpower, the Bureau of Health Services, the Social Security Administration, the Office of Education, and the Social and Rehabilitation Service; and other Government agencies, particularly the Office of Economic Opportunity, the Model Cities Program of the Department of Housing and Urban Development, and the Veterans Administration. New sources of possible support for activities related to a Regional Medical Program should be considered during both the planning and operational phases.

²The Regional Advisory Group should provide overall advice and guidance in the planning and operational Program, from the initial steps onward. It should be actively involved in the review and guidance and in the coordinated evaluation of the ongoing planning and operating functions. It should be constituted to encourage cooperation among the institutions, organizations, health personnel, and state and local health agencies such as the health planning bodies being established under the Comprehensive Health Planning Program, Public Law 89-749 as amended. It should be concerned with continuing review of the degree of relevance of the planning and operational activities to the objectives of the Regional Medical Program and particularly with the effectiveness of these activities in attaining the goal of improved patient care. The Advisory Group does not have direct administrative responsibility for the Program, but the clear intent of the Congress was that the Advisory Group would insure that the Regional Medical Program is planned and developed with the continuing advice and assistance of a group which is broadly representative of the health interests of the Region. The Advisory Group is expected to prepare an annual statement giving its evaluation of effectiveness of the regional cooperative arrangements established under the Regional Medical Program.

needs must be stated in terms which offer opportunities for solution.

This process of identification of needs and opportunities for solution requires a continuing analysis of the problems in delivering the best medical care for the target diseases on a regional basis, and it must go beyond a generalized statement to definitions which can be translated into operational activity. Particular opportunities may be defined by: ideas and approaches generated within the Region, extension of activities already present within the Region, and approaches and activities developed elsewhere which might be applied with the Region.

Among various identified needs there also are often relationships which, when perceived, offer even greater opportunities for solutions. The danger of "project vision," which is akin to tunnel vision, must be guarded against.

In examining the problem of coronary care units throughout its Region, for example, a Regional Program may recognize that the more effective approach would be to consider the total problem of the treatment of myocardial infarction patients within the Region. This broadened approach on a regional basis enables the Regional Program to consider the total array of resources within its Region in relationship to a comprehensive program for the care of the myocardial infarction patient. Thus, what was a concern of individual hospitals about how to introduce coronary care units has been transformed into a project or group of related projects with much greater potential for effective and efficient utilization of the Region's resources to improve patient care.

Assessment of Resources—As part of the process of regionalization, a Region must have continuously updated inventory of existing resources and capabilities in terms of function, size, number and quality. Every effort should be made to identify and use existing inventories, filling in the gaps as needed, rather than setting out on a long, expensive process of creating an entirely new inventory. Information sources include state and local health planning agencies, hospital and medical associations, and voluntary agencies. The inventory provides a basis for informed judgments and priority setting on activities proposed for development under the Regional Program. It can also be used to identify missing resources—voids requiring new investment—and to develop new configurations of resources to meet needs.

Definition of Objectives—A Regional Program must be continuously involved in the process of setting operational objectives to meet identified needs and opportunities. Objectives are interim steps toward the Goal defined at the beginning of this Chapter, and achievement of these objectives should have an effect in the Region felt far beyond the focal points of the individual activities. This can be one of the greatest contributions of Regional Medical Programs. The completion of a new project to train nurses to care for cancer patients undergoing new combinations of drug and radiation therapy, for example, should benefit cancer patients and should provide additional trained manpower for many hospitals in the Region. But the project also should have challenged the Region's nursing and hospitals communities to improve the continuing and in-service education opportunities for nurses within the Region.

Setting of Priorities—Because of limited manpower, facilities, financing and other resources, a Region must assign some order of priority to its objectives and to the steps to achieve them. Besides the limitations on resources, factors to consider include: 1) balance between what should be done first to meet the Region's needs, in absolute terms, and what can be done using existing resources and competence; 2) the potentials for rapid and/or substantial progress toward the Goal of Regional Medical Programs and progress toward regionalization of health resources and services; and 3) Program balance in terms of disease categories and in terms of emphasis on patient care, education and research.

Implementation—The purpose of the preceding steps has been to provide a base and imperative for action. In the creation of an initial operational program, no Region can attempt to determine all of the program objectives possible, design appropriate projects to meet all the objectives and then assign priorities before seeking a grant to implement an operational program which encompasses all or even most of the projects. Implementation can occur with an initial operational program encompassing even a small number of well-designed projects which will move the Region toward the attainment of valid program objectives. Because regionalization is a continuous process, a Region is expected to continue to submit supplemental and additional operational proposals as they are developed.

After the implementation of an operational program, there are two potential threats to be avoided. One is that projects will lose their regional identities by becoming institutional projects, and thereby cancel the opportunity for the operational program to have Regional scope and effect. The other threat is that projects will lose the relationships one to another which maintain the interaction of patient care, education, and research. Preventing these breakdowns requires project and program administration of a high order; it also requires sustained communications, involvement, and the application of evaluation procedures.

Evaluation—Each planning and operational activity of a Region, as well as the overall Regional Program, should receive continuous, quantitative and qualitative evaluation wherever possible. Evaluation should be in terms of attainment of interim objectives, the process of regionalization, and the Goal of Regional Medical Programs.

Objective evaluation is simply a reasonable basis upon which to determine whether an activity should be continued or altered, and ultimately, whether it achieved its purposes. Also, the evaluation of one activity may suggest modifications of another activity which would increase its effectiveness.

Evaluation implies carrying out whatever is fea-

sible within the state of the art and appropriate for the activity being evaluated. Thus, evaluation can range in complexity from simply counting numbers of people at meetings to the most involved determination of behavioral changes in patient management.

As a first step, however, evaluation entails a realistic attempt to design activities so that, as they are implemented and finally concluded, some data will result which will be useful in determining the degree of success attained by the activity.

Criteria—Evaluation of Regional Medical Programs—The criterion for judging the success of a Region in implementing the process of regionalization is the degree to which it can be demonstrated that the Regional Program has implemented the seven essential elements discussed in this Chapter: involvement, identification of needs and opportunities, assessment of resources, definition of objectives, setting of priorities, implementation, and evaluation.

Ultimately, the success of any Regional Medical Program must be judged by the extent to which it can be demonstrated that the Regional Program has assisted the providers of health services in developing a system which makes available to everyone in the Region improved care for heart disease, cancer, stroke, and related diseases.

Chapter III

GRANT POLICIES

I. Eligible Applicant

Public or nonprofit private universities, medical schools, research institutions and other public or nonprofit private agencies and institutions are eligible to apply for a grant to plan and/or operate a Regional Medical Program. Each applicant must be authorized to represent the agencies and institutions which propose to cooperate in planning for and development of the Regional Program. Additionally, each applicant must be able to exercise program coordination and fiscal responsibility (see agreement of affiliation, Chapter III, p. 14). Finally, each applicant in order to be eligible must have designated a Regional Advisory Group to advise the applicant (and those agencies and institutions which propose to cooperate in the Regional Medical Program) in the planning and operation of the Program.

It may be necessary for the agencies and institutions proposing to cooperate in the Program to create a nonprofit corporation to act for them as the applicant, to maximize the extent to which effective program and fiscal coordination can be exercised in the implementation of the Regional Program.

II. Types of Grants

Planning—Section 903 of The Act authorizes the Surgeon General, upon recommendation of the National Advisory Council on Regional Medical Programs, to make grants to assist in the planning and development of Regional Medical Programs.

Operational—Section 904 of The Act authorizes the Surgeon General, upon recommendation of both the Regional Advisory Group and the National Advisory Council on Regional Medical Programs, to make grants to assist in the establishment and operation of Regional Medical Programs.

The planning activities which are initially funded under the provisions of Section 903 may be continued and expanded as an integral part of the operational activities of each Region and as

such may become a part of the Region's operational grant under Section 904. However, operational activities may not be supported from planning grant funds.

Recognizing the necessity for each Region to plan ahead, the various Regional Medical Programs are encouraged to consider their phasing according to the nature and extent of the activities involved up to a maximum of five years.

The commitment for support beyond June 30, 1969, is based upon anticipated renewal of the Regional Medical Program's authorizing legislation and is predicated on the annual appropriation of funds by the Congress. Commitments beyond the terminal dates of legislation—both appropriations and authorizing legislation—are delimited by the phrase, "within the limits of available funds," written into the regulations and on the award statements issued by the Division.

III. The Regional Advisory Group

The Act specifies that an applicant for a planning grant must designate a Regional Advisory Group. The Act also specifies that the Advisory Group must approve an application for an operational grant under Section 904. The Advisory Group must include practicing physicians, medical center officials, hospital administrators, representatives from appropriate medical societies, other health professions, voluntary health agencies, and representatives of other organizations, institutions, and agencies, and members of the public familiar with the need for the services provided under the Program. It should also be broadly representative of the geographic area and of the social groups who will be served by the Regional Medical Program.

The Regional Advisory Group should provide overall advice and guidance to the grantee in the planning and operational program from the initial steps onward. It should be actively involved in the development of the Regional objectives, as well as

the review, guidance, and coordinated evaluation of the ongoing planning and operating functions. It should be constituted to encourage cooperation among the institutions, organizations, health personnel, state and local health agencies. It should be concerned with continuing review of the degree of relevance of the planning and operational activities to the objectives of the Regional Medical Program and particularly with the effectiveness of these activities in attaining the objective of improved patient care. Therefore, Advisory Group members should be chosen who will provide a broad background of knowledge, attitudes and experience.

To serve these purposes, the Advisory Group should operate under established procedures which insure continuity and appropriate independence of function and advice. It should formally consider what its specific duties and responsibilities shall be, including such things as the frequency of its meetings and appropriate methods for the replacing of retiring members.

The Advisory Group, through the grantee, must submit to the Division of Regional Medical Programs an annual statement giving its independent evaluation of effectiveness of the regional cooperative arrangement (regionalization) established under the Regional Medical Program.

IV. Assurances

General Responsibilities—The grantee is obligated, both for itself and each affiliated institution, to administer the grant in accordance with regulations (Appendix 2) and policies of the Division of Regional Medical Programs. Where a policy is not stated or where the institutional policy is more restrictive than the Regional Medical Program policy, institutional policy prevails in that institution.

General Assurances—Specific attention is directed to the requirement to honor the assurances provided in the Act.

The recipient of a planning grant must comply with the assurances in Section 903 (b), namely:

- reasonable assurances that Federal funds paid pursuant to any such grant will be used only for the purposes for which awarded and in accordance with the applicable provisions of The Act and the regulations thereunder;

- reasonable assurances that the applicant will provide for such fiscal control and fund accounting procedures as are required by the Surgeon Gen-

eral to assure proper disbursement of and accounting for such Federal funds;

- reasonable assurances that the grantee will make such reports in such form and containing such information as the Surgeon General may from time to time reasonably require, and will keep such records and afford such access thereto as the Surgeon General may find necessary to assure the correctness and verification of such reports; and

- a satisfactory showing that the applicant has designated an advisory group to advise the applicant (and the institutions and agencies participating in the resulting Regional Medical Program) in formulating and carrying out the plan for the establishment and operation of such Regional Medical Program, which advisory group includes practicing physicians, medical center officials, hospital administrators, representatives from appropriate medical societies, voluntary health agencies, and representatives from other organizations, institutions and agencies concerned with activities of the kind to be carried on under the Program and members of the public familiar with the needs for the services provided under the Program.

The recipient of an operational grant must comply with the assurances under Section 904 (b), namely:

- Federal funds paid pursuant to any such grant (A) will be used only for the purposes for which paid and in accordance with the applicable provisions of this title and the regulations thereunder, and (B) will not supplant funds that are otherwise available for establishment or operation of the Regional Medical Program with respect to which the grant is made;

- the applicant will provide for such fiscal control and fund accounting procedures as are required by the Surgeon General to assure proper disbursement of and accounting for such Federal funds;

- the applicant will make such reports, in such form and containing such information as the Surgeon General may from time to time reasonably require, and will keep such records and afford such access thereto as the Surgeon General may find necessary to assure the correctness and verification of such reports; and

- any laborer or mechanic employed by any contractor or subcontractor in the performance of work on any construction aided by payments pur-

suant to any grant under this section will be paid wages at rates not less than those prevailing on similar construction in the locality as determined by the Secretary of Labor in accordance with the Davis-Bacon Act, as amended (40 U.S.C. 276a-276a-5); and the Secretary of Labor shall have, with respect to the labor standards specified in this paragraph, the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (15 F.R. 3176; 5 U.S.C. 133z-15) and section 2 of the Act of June 13, 1934, as amended (40 U.S.C. 276c).

V. Eligible Activities

Categorical Emphasis—The focus of Regional Medical Programs under the authorizing legislation is on problems of heart disease, cancer, stroke and related diseases. This broad categorical approach must be a consideration in the development of specific Program elements under a Regional Medical Program. Because of the broad scope of heart disease, cancer, and stroke, it would be difficult and perhaps detrimental to some types of medical services and educational activities if a rigidly categorical approach were adopted for all relevant Program elements. The emphasis of the Program does require that the component elements be shown to have significance for combating heart disease, cancer, stroke and related diseases through a regional effort intended to improve the care of all those persons within the Region suffering from one of these diseases. However, in some instances, activities which have a more general impact extending beyond the specific problems of heart, cancer, stroke and related diseases may need to be supported because they are essential to the achievement of the purposes of Regional Medical Programs.

The objective of improved patient care for those suffering from these categorical diseases will require the full development of the process of regionalization, particularly in the Program's operational phases. Therefore, individual, categorical activities should be designed and implemented in ways which will insure their regional rather than organizational or institutional identity.

Core Support—The central administration and coordination of a Regional Medical Program represents the administrative heart of the Program, and as such is an activity eligible for grant support. The salaries of the Program Coordinator

and his staff as well as other costs incident to the central administration and coordination of the Program may be charged to the grant.

Research—Research activities which are integral to the purposes and objectives of the Regional Medical Program are eligible for support and their costs may be paid by grant funds. Such research activities in order to be eligible must contribute to the process of regionalization and the goal of improved patient care the Program seeks to achieve.

Demonstrations of Patient Care—Demonstrations of patient care may be supported when related to the objectives of the Regional Medical Program. The Act provides that the costs of patient care may be supported only when such care is incident to research, training, or demonstration activities encompassed by the purposes of the Program and only if the patient has been referred by a practicing physician. Documentation must be provided (see Chapter III, page 15). Such demonstrations must contribute to the process of regionalization and the goal of improved patient care which the Regional Program is seeking to achieve. Grant funds may be used to pay the other costs incident to the demonstration activity, including staff and equipment.

Training and Continuing Education—Continuing education and training programs for medical, allied health personnel and associated professions which are part of integrated comprehensive approaches of enhancing regional capability for the diagnosis and treatment of heart disease, cancer, stroke, and related diseases are eligible for support. However, it should be emphasized that the primary intent of the legislation in this area is the support of those activities that are beyond those normally accepted as basic preparation for work in the health field. If one is to make assessment of needs for educational programs, this assessment must be based on the system of health care, the role of the learner, and his needs. In medical education, attention must be focused directly on the questions: "Will this effort to change behavior result, in fact, in the patient receiving the maximum benefit of modern knowledge?". Grant funds may be used for innovative training approaches and the development of new types of health personnel or new arrangements of health personnel to meet the Region's goal of improved patient care for those suffering from heart disease, cancer, stroke, or related diseases.

Systems Analysis—The use of systems analysis methodologies in Regional Medical Programs is eligible for grant support, but only to such an extent as it is considered applicable as an essential integral component of the individual program proposed by the applicant. The applicant should emphasize the development of innovative, adequately formulated studies of realistically restricted problems involving the application of "systems" methodologies rather than submit an application dominated by general proposals for the utilization of large scale "systems" approaches for the design of a Regional Program. These methodologies may be applied to either or both planning and operational activities.

Communications and Public Information—A communications and public information component can be included as an integral part of a Regional Medical Program. A qualified communications and public information specialist and necessary supporting staff may be employed to utilize all established communications and informational techniques to assist in the development of Regional Program activities which will achieve understanding, acceptance, support and cooperation of institutions, organizations and individuals in the initial growth period of the Regional Program. Then, in the operational phase, this staff can mount an additional effort toward these same ends which will not only maintain these relationships, but expand them to include all participating and benefitting publics. Activities that do not specifically advance understanding, acceptance, support and cooperation, or which would appear to provide only for publicity for the Program and aggrandisement of its officials, should not be included.

VI. Specific Requirements

Discrimination Prohibited—Section 601 of Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d, provides that no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. Regulations implementing the statute have been issued as Part 80 of Title 45, Code of Federal Regulations. The Regional Medical Programs provide Federal financial assistance subject to the Civil Rights Act and the regulations.

It is the responsibility of the grantee to insure that each affiliated agency (institution) which pro-

poses to cooperate in the Regional Medical Program is in compliance with Section 601 of Title VI of the Civil Rights Act of 1964. The grantee shall maintain a copy of the form which insures that each affiliated agency (institution) is in compliance.

Each grant for construction (alterations and renovation) is subject to the condition that the grantee shall comply with the requirements of the Executive Order 11246, 30 F.R. 12319 and the applicable rules, regulations, and procedures as prescribed by the Secretary of Labor.

Institutional Assurance Involving Human Subjects—An application for a Regional Medical Program grant which includes investigations involving human subjects will not be accepted for review unless the Public Health Service has approved a plan (known as Institutional Assurance on Investigations Involving Human Subjects, Including Clinical Research and Investigations in the Behavioral and Social Sciences) for insuring that the institution conducting the research has complied with the Public Health Service policy concerning research involving human subjects.

It will be the responsibility of the grantee to insure that the individual affiliated institution(s) which will be involved in these investigations secure the approval from the Public Health Service and to provide a copy of the approval to the Division of Regional Medical Programs.

A copy of the Instructions for obtaining Public Health Service approval may be obtained by writing the Grants Review Branch, Division of Regional Medical Programs, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20014.

Surveys or Questionnaires—Surveys or questionnaires arising from and supported by a grant should include a positive statement clearly setting forth that the contents are in no way the responsibility of the Public Health Service. They should conform with Bureau of the Budget, Circular # A-40.

Publications—Grantees and/or their affiliated institutions may publish materials relating to their Regional Medical Program without prior review provided that such publications carry a footnote acknowledging assistance from the Public Health Service, and indicating that findings and conclusions do not necessarily represent the views of the Service.

Patents and Inventions—The Department of Health, Education, and Welfare regulations (945 F.R., Part 6 and 8) provide as a condition that all inventions arising out of the activities assisted by Public Health Service Grants must be promptly and fully reported to the Public Health Service. Any process, art or method, machine manufacture or improvement thereof, may constitute an invention if it is new and useful and would not have been obvious to a person having skill in the art to which it relates.

In order for the Public Health Service to carry out its responsibility under these patent regulations, it is essential that the Service be advised before awarding Government funds of any commitments or obligations made by the institutions or by the professional personnel to be associated with the activities carried on under the grant which would be in conflict with the inventions agreement. When submitting an application for a Regional Medical Program, the grantee must provide in letter form either:

- a. a statement indicating no previous commitments or obligations have been made, or
- b. a detailed explanation of such commitments or obligations where they do exist.

One such letter will suffice for the named grantee and all affiliated institutions receiving support under the grant. It is the responsibility of the institution named as the grantee on the application to ascertain the facts relating to patents and to report these on behalf of all affiliated organizations in the Regional Medical Program as well as to inform affiliated institutions of these responsibilities.

In subsequent years an annual invention statement form PHS-3945 must be filed whether or not an invention has occurred. Where there are no inventions to report, a single form PHS-3945 is all that is required for the institution named on the application as the grantee and for all affiliated institutions. Where there are inventions to report, a separate annual invention statement must be filed for each one. Here again, it is the responsibility of the grantee to report on behalf of itself and all other affiliated organizations in the Regional Medical Program. The Regional Medical Program grant for the next year will not be issued until the invention statement form PHS-3945 has been received by the Division of Regional Medical Programs.

Animal Care—Each person assigned or ap-

pointed to an activity receiving any Public Health Service support is required to exercise every precaution to assure proper care and humane treatment of research animals. The booklet, Guide for Laboratory Animals, Facilities and Care (PHS Publication #1024) should be obtained from the Division of Research Grants, Information Office, National Institutes of Health, Bethesda, Maryland 20014.

The Public Health Service endorses the following guiding principles in the care and use of animals:

(1) Animals should be acquired, retained, and used in compliance with applicable state and local law.

(2) Animals should receive every consideration for their bodily comfort, be kindly treated and properly fed, be kept in sanitary facilities, and be provided with suitable medical care.

(3) With any operation likely to cause greater discomfort than that attending anesthetization, the animal should first be rendered incapable of perceiving pain and should be maintained in that condition until the operation is ended. Exceptions should be made only when anesthesia would defeat the objective of the experiment. In such cases, the anesthesia should be discontinued only so long as it is absolutely essential for the necessary observations.

(4) If the nature of the study requires survival of the animal, aseptic precautions should be observed during the operation, and care should be taken to minimize discomfort during convalescence comparable to precautions taken in a hospital for human beings. If the animal is severely incapacitated and survival is not a requirement of the experiment, the animal should be sacrificed in a humane manner immediately following final observation.

Change in Approved Program—The Division of Regional Medical Programs does not intend to interfere with administrative or program flexibility which serves the objectives of the Regional Medical Programs. If, however, a change is determined by the grantee to be desirable, and if that change would constitute a substantial change in the nature of the Program originally approved, the grantee must consult with the Division of Regional Medical Programs staff. No substantial change in the approved Program can be made without the specific written approval of the Division of Regional Medical Programs. Requests for

such approval must be submitted in an *Application for Revision* (page 21).

Change in Program Period—The Program period may be extended up to 12 months without additional funds, if requested by the grantee before the end of the Program period.

Change of Program Coordinator—A change of Program Coordinator or other key official directing the Program requires the written approval by the Division of Regional Medical Programs. Notification to the Division of Regional Medical Programs of such a proposed change must be signed by at least one of the two persons who signed the original application or their successors. A curriculum vitae for the newly appointed official should accompany the notification of change.

Change of Grantee Organization—If for any reason the grantee organization proposes to relinquish its responsibility for a Regional Medical Program grant, it must immediately notify the Division of Regional Medical Programs. For example, a region may wish to create a non-profit corporation especially for the purpose of becoming the grantee organization. Any change of grantee organization requires that a terminal progress report, an expenditures report, and an invention statement (PHS-3945) be submitted to the Division of Regional Medical Programs.

If the grantee terminates its responsibility for the Regional Medical Program, the new institution/corporation must submit a new grant application for the remainder of the program period. The application should include the reasons for transferring the Program and the probable effect of the move on the Regional Program. Administrative approval may be given by the Division of Regional Medical Programs to continue the Program with a new grantee. Applications, however, that reflect major Program changes will be referred to the National Advisory Council on Regional Medical Programs for recommendation.

Early Termination of Grant—(1) By the Grantee—A grant may be terminated or cancelled at any time by the grantee upon written notification to the Division of Regional Medical Programs stating the reasons for termination.

(2) By the Public Health Service—A grant in whole or in part, may be revoked or terminated by the Surgeon General at any time within the program period whenever it is determined that the

grantee has failed in a material respect to comply with the terms and conditions of the grant.

Single Grantee—In order to insure regional cooperation, there can be only a single grantee organization for each Regional Medical Program.

Reports—All reports required to be submitted to the Public Health Service should be sent to the Division of Regional Medical Programs, Public Health Service, Bethesda, Maryland 20014.

A. Progress Reports—The grantee is required to submit an annual progress report for each grant. This report (s) should contain sufficient detail to inform the reader of the accomplishments with particular respect to the objectives and must be submitted with the application for continued support. In addition, grantees may be required to supply other information needed for guidance and development of the national program and are encouraged to report significant developments promptly at any time. A terminal progress report must be submitted to the Division of Regional Medical Programs within three months of the termination of the program period. Specifically, the report must describe the ways in which the process of regionalization as described in Chapter II has moved the Regional Program toward its goal of improved patient care for all those within the Region suffering from heart disease, cancer, stroke, or related diseases. The report must also include:

- (1) principal staff members—names and positions
- (2) organization of the Regional Medical Program
- (3) membership and functions of the Regional Advisory Group
- (4) names of all cooperating agencies/institutions and their relationship to the Regional Medical Program
- (5) description of planning activities
- (6) description of operational activities, if any
- (7) description of interregional activities, if any
- (8) the extent to which the planning and operational activities of the Program are supported by non-Federal funds.

B. Regional Advisory Group Reports—The Regional Advisory Group is expected to prepare an annual statement on the effectiveness of the regional cooperative arrangements (regionalization) established under the Regional Medical Program. The report, signed by the Chairman of the

Regional Advisory Group, signifying its approval, should be submitted to the Division of Regional Medical Programs by the grantee along with the annual progress report. Periodic reviews of grants by the staff of the Division and the Advisory Council will include consideration of the effectiveness of the Advisory Group.

VII. Financial Management

General Requirements—Federal funds awarded pursuant to either a planning or operational grant are to be used only for the purposes for which awarded and in accordance with the provisions of the Act (Appendix 1), its regulations (Appendix 2), and these *Guidelines*. Additionally, Federal funds awarded pursuant to an operational grant may not be used to supplant funds that are otherwise available for the establishment or operation of the Regional Medical Program with respect to which the grant is made.

Funds granted may be used only for services, materials and other items required to carry out the approved program. Circular A-21 of the Bureau of the Budget should be used to the extent practicable in determining allowable costs related to the grants for Regional Medical Programs. Where the Division of Regional Medical Programs requires prior approval for items not listed in the approved budget, a written request must be made by the grantee to the Division of Regional Medical Programs in advance of the act which requires the obligating or expenditure of funds.

Agreement of Affiliation—By accepting a Regional Medical Program grant, the grantee has accepted certain responsibilities enumerated on pages 9-10 of this Chapter. However, the Regional Medical Program activities will necessitate the expenditure of grant funds by a number of different institutions, organizations, and agencies in addition to the grantee. In order to assure appropriate accountability for the expenditure of grant funds by these additional agencies, an Agreement of Affiliation must be signed by the responsible official of each affiliating institution (or agency) and by the grantee who represents the Regional Medical Program. Such an agreement will not be required nor appropriate in the conduct of business with (1) a profit-making organization by subcontract, or, (2) where direct payment is to be made for the use of facilities or for services rendered on behalf of the Regional Medical Program. This agreement, at a minimum, must

include provision which will insure that the grantee can carry out the assurances required by the Act in Sections 903 (b) and 904 (b) and that the grant funds provided to each affiliated agency will be administered by that agency in accordance with the Act, the regulations and applicable policies of the Division of Regional Medical Programs (see example—Appendix 3):

The Division also encourages the Regional Medical Program to include in such agreement any provisions relating to the conduct and development of the Regional Medical Programs as may be appropriate and desirable for the achievement of the purposes of the Program as outlined in these *Guidelines*. The advice and counsel of the Regional Advisory Group should be sought in developing such provisions.

Allowable Direct Costs—

A. **Personnel Costs**—Salaries and wages of personnel in proportion to the time or effort expended on activities of the Regional Medical Program may be charged to the grant. These costs must be in accordance with applicable institutional policies, and adequate time and effort records must be maintained in order to substantiate these costs. Salaries of personnel whose full time is devoted to the Regional Medical Program should not exceed the salaries of full-time administrative personnel in positions of comparable responsibility in major medical institutions in the Region. Specifically, if a new corporation is organized to serve as the grantee, it must establish salary policies which apply to its personnel under the above policies and which do not exceed equivalent salaries in the major medical institutions in the Region.

Any question concerning the appropriateness of particular salaries or exceptions to these policies should be discussed with the Division Staff.

B. **Consultant Services**—Regional Medical Program grant funds may be used to pay consultant fees and supporting costs such as travel, and per diem in payment for services related to any Program element of a Regional Medical Program, providing that these services are the most effective means of accomplishing a particular purpose.

- If consultation is obtained from a salaried staff member of the grantee or an affiliated institution, that institution may be reimbursed for a proportionate amount of his regular salary from grant funds. Program records must indicate the total cost and include a statement of activities.

- Where justified by unusual circumstances, a salaried staff member of the grantee or an affiliated institution who is not receiving salary support from the grant, may be engaged as a consultant, but only with the prior approval of the Division of Regional Medical Programs. The Request for approval must be supported by a clear statement of services to be performed and the expected number of days of service involved.

- Grant funds may not be used to pay fees and supporting costs to U.S. Government employees, regardless of their employment or pay status.

C. Training Activities—

(1) Selection of Trainees—Selection of trainees is the responsibility of the Region. The Division of Regional Medical Programs must be notified of the number and kinds of trainees that start and complete a training program.

Training activities are eligible for grant support according to the following general conditions:

a. Training Conferences and Seminars: No stipends may be paid for presentations which are planned for full-time participation for periods from one full day to five consecutive days or intermittently on a regular basis. However, travel and other expenses associated with these presentations may be paid.

b. Short-Term Training: These activities include full-time training programs for more than five consecutive days but not more than a single academic session (quarter or semester). For allied health trainees either a stipend may be paid or the trainee may be reimbursed in accordance with a maintenance of income principle which would have the effect of reimbursing the trainee at the level of his individual salary.

Physician and dentist trainees may be compensated at a rate not to exceed \$50.00 per day.

Travel and other expenses associated with short-term training programs may be paid for any trainee.

c. Long-Term Training: These activities include training programs requiring full-time participation for more than a single academic session (quarter or semester). Stipends and travel expenses may be paid to those enrolled in long-term training programs. These stipends vary according to the level of training and are consistent with other equivalent Public Health Service training programs.

Detailed information and policies con-

cerning all eligible training activities will be supplied upon request by the Division of Regional Medical Programs.

D. Patient Care Costs (Hospitalization)—The cost of hospital care of patients is payable from grant funds only to the extent that such care is incident to research, training, or demonstration activities supported by the grant (Chapter III, page 10). If grant funds are used to support costs associated with hospitalization the grantee must document in each case that the patient has been referred by a practicing physician, including his name, the name of the patient, and the date of referral. The calculation of a rate of reimbursement will be according to established Public Health Service policies which can be made available to the grantee upon request.

E. Transportation of Patients—When justified as the most efficient means of carrying out the purpose of the Program, grant funds may be used to pay the costs of transportation of patients with escort referred for diagnosis and treatment in other institutions as part of a research, training or demonstration program. The use of grant funds to pay transportation costs should be carefully weighed against use of funds for other activities within the Regional Medical Program.

F. Alterations and Renovations—To the extent that other sources of Federal and non-Federal funds are not readily available to the applicant for such purposes, ninety percent of the costs of construction, i.e., alteration, remodeling and renovation of existing buildings (including initial equipment thereof) and replacement of obsolete built-in equipment of the types customarily included in a construction contract may be paid for by operational grant funds. The applicant is required to furnish a narrative description to indicate the need, nature and purpose of the proposed alterations and renovations, and, in appropriate instances, detail the plans and specifications. The amount of the alteration and renovation costs requested as part of a Division of Regional Medical Programs grant determines the types of supporting documents to be submitted by the applicant. Applicants are referred to the procedures and regulations set forth in the "Regional Medical Programs—Alterations and Renovations Guide," available on request.

G. Electronic Communication Systems—A grant may support the purchase or rental of electronic communication systems such as special tele-

phone lines, radio and television, to be used for educational, diagnostic or other purposes. However, if such requests represent major funding investments, they should include documentation of: the planned measurements of effectiveness of the activity; the numbers of people affected by the system; the degree to which the program content and experience might be generalized to other Regional Medical Programs; and knowledge of related efforts already accomplished by others with indications as to how the proposed activity will extend those efforts.

H. Telephone, Postage and Similar Services—That portion of telephone, postage and other such services necessary to the planning or implementation of the Regional Program may be charged to the grant. In no case may institutional local and regular monthly telephone costs and normal postage costs not related to the Regional Medical Programs be charged to the grant.

I. Design, Printing and Reproduction—The costs of pamphlets, brochures and other necessary materials may be charged to the grant.

J. Equipment—Rental and purchase of equipment, including diagnostic and treatment equipment, for the planning or implementation of a program may be charged to the grant. When acquiring equipment, consideration of the relative advantages of lease versus purchase should be considered.

K. Computers—Grant funds may be used to purchase computer time, or if the needs of the program are sufficient, the rental of a computer. As with all other activities, the costs of acquiring computer capability must be measured against the benefits to be derived.

L. Travel—Per diem reimbursements to travelers, personal transportation charges, and reimbursements for authorized use of personally owned automobiles are chargeable to the grant. If a corporation is established for the purpose of becoming the grantee, it must establish travel policies which apply to its personnel under the above policy and which do not exceed the equivalent travel policies of the major medical institutions in the Region.

Less than first class travel accommodations shall be used except in extenuating circumstances. Automobile mileage and any foreign travel must be in accordance with institution policy. Any foreign travel must receive prior approval from the Division of Regional Medical Programs.

M. Rent—The expenses for rental of facilities not owned by the grantee or affiliated institution may be charged in proportion to the space actually utilized for the Regional Program activity. Rental costs may not be in excess of comparable rentals in the particular locality, and must be in accordance with institution policy.

Direct Costs Not Allowed—The following direct costs or charges are not allowable:

(1) Honoraria as distinguished from consultant fees

(2) Entertainment (cost of amusement, social activities, entertainment and incidental costs thereto, such as meals, lodging, rentals, transportation and gratuities)

(3) Payment to Federal employees

(4) Petty cash funds

(5) Subgranting (a subgrant is any allocation of grant funds by the grantee to other individuals or organizations for purposes over which the grantee institution named on the application does not maintain scientific and financial responsibility. A grantee may contract for services, but may not subgrant).

Indirect Costs—Indirect costs related to the conduct of the Regional Medical Program are reimbursable. To be eligible for reimbursement, an indirect cost proposal must be developed by the performing institution in conformity with its established accounting system and submitted to the Division of Regional Medical Programs. The proposal must identify those administrative services provided to the program during the institution's fiscal year, the costs of the services and the basis or methods for apportioning those costs to the Regional Medical Program and other activities of the institution. A new proposal must be submitted at the end of each fiscal year.

The Department of Health, Education, and Welfare has published separate guides for establishing indirect cost rates applicable to educational institutions, hospitals, State and local government agencies, and other non-profit institutions which provide guidelines and criteria for the identification of indirect costs reimbursable under research grants and contract, and for apportionment of administrative costs to the major operating activities of the institution. The booklets contain cost principles which define direct and indirect costs and provide information on the allowability of specific items of cost. They describe methods of cost apportionments and allocations, instructions

on the development of indirect cost rates and sample indirect cost proposals. Although oriented primarily toward the research activity, the policies and criteria contained therein are relevant to the Regional Medical Program and should be used as a guide.

Institutions performing under Regional Medical Program grants may also be the recipient of grants or contracts under other Federal programs. It is essential that consistent procedures for determining reimbursable costs for similar services be employed without regard to program differences. Additional information and assistance may be obtained from the Division of Regional Medical Programs, National Institutes of Health, Bethesda, Maryland 20014. The Department of Health, Education, and Welfare cost guides may be obtained from the Government Printing Office, North Capital between G & H Streets, N.W., Washington, D.C. 20402.

Rebudgeting of Funds—The grantee or affiliated institutions with full knowledge and approval of the grantee may depart from the approved budget and use the funds for other items required for the project, except for the following restrictions:

(1) Grant funds may not be used for any purpose contrary to the regulations and policies of the Division of Regional Medical Programs or the grantee or the affiliated institutions.

(2) Grant funds may be transferred between budget categories within projects or activities only to the extent that no substantial change in any such project is made by the transfer (see changes in approved program, page 12). Budget changes between projects or other identified activities however, require written approval of the Division of Regional Medical Programs. Rebudgeting should not be done within the period between submission of a continuation application and receipt of the award, and required special justification and written approval from the Division of Regional Medical Programs under exceptional circumstances.

Refunds—During the program period, refunds and rebates should be credited to the grant account. Credits received after the termination of the program period shall be returned to the Public Health Service. Checks should be made payable to Public Health Service, Department of Health, Education, and Welfare, and transmitted to the Division of Regional Medical Programs.

(1) Interest and Other Income—Interest or

other income earned on grant funds must be returned to the Public Health Service.

(2) Royalties and Profits—When the costs of publishing material are provided from Public Health Service grants, any royalties or profits up to the amount charged to the grant for publishing the material shall be refunded to the Public Health Service.

Unexpended Balance—No funds may be carried forward from one budget period to another unless:

(1) They are included as part of the budget of the continuation grant application, and

(2) The expansion of the Program beyond that upon which the commitment of funds was based is clearly justified in terms of the relevance of the expansion to the Program areas originally approved as part of the original grant. Approval of such a request will frequently require approval by the National Advisory Council.

Obligations or Expenditures—Obligations, commitments, encumbrances, or expenditures will normally be made within the period indicated on the notice of grant award. Grant funds may not be used to reimburse any such obligations, commitments or expenditures made prior to the beginning date of the initial grant for a new or renewal project. In exceptional instances the grantee may, at its own risk, prior to the beginning date of a continuation award, incur expenditures which exceed existing Division of Regional Medical Programs authorization but which are considered essential to the conduct of the Program. The Division of Regional Medical Programs may allow reimbursement of such expenditures from the continuation grant.

Accounting, Records, and Audit—

(1) Accounting—Accounting for grant funds will be in accordance with the grantee and/or affiliated institution accounting practices consistently applied regardless of the source of funds. Itemization of all supporting expenditures must be recorded in sufficient detail to show the exact nature of expenditures. Each recipient of grant funds shall keep such records as the Surgeon General may prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the program or undertaking in connection with which such grant is made or used, and the amount of the portion of the cost of the program or undertaking supplied by other sources,

and to make such records available as will facilitate an effective audit by authorized personnel. Such a system must meet the following criteria:

a. A special grant account must be established for each Regional Medical Program grant and be maintained at the grantee institution designated on the application. Responsibility for expenditure of funds by affiliated institutions must be assumed by the grantee.

b. The grantee's accounting records shall provide the information needed to identify the receipt and expenditure of all program funds separately for each grant. Expenditures shall be recorded by the component program and budget cost categories shown in the approved budget.

c. Each entry in the accounting records at the grantee or affiliated institution shall refer to the documentation which supports the entry and the documentation shall be filed in such a way that it can be readily located.

d. The accounting records shall provide accurate and current financial reporting information.

e. The accounting system shall possess an adequate means of internal control to safeguard the assets, check the accuracy and reliability of the accounting data, promote operational efficiency, and encourage adherence to prescribed management policies.

(2) Records—The financial records, including all documents to support entries on the accounting records, must be kept readily available for examination by authorized personnel. No such records shall be destroyed or otherwise disposed of within six years after the termination of the budget period. Unless written approval is obtained from the Public Health Service to dispose of the records, they must be retained until the audit has been completed and all questions about the expenditures are resolved.

(3) Audit—The Department of Health, Education, and Welfare follows generally accepted auditing practices in determining that there is a proper accounting in use of grant funds. Failure of a grantee to appeal a proposed audit disallowance within thirty days after receipt of a written notification will make the action conclusive.

Equipment (Title and Accountability)—Title to equipment purchased with grant funds resides in the grantee and accountability may be satisfied after the termination of the grant by the Division

of Regional Medical Programs as long as the equipment is used to further the objectives of the Public Health Service. The Division of Regional Medical Programs, however, reserves the right under unusual circumstances to transfer title of equipment to the Division of Regional Medical Programs or to another grantee.

Excess materials and supplies retained by the grantee upon termination of the program may be accounted for under the same terms as equipment.

Reports—

(1) Expenditures Report (Form NIH 925-3)—A single expenditures report and a single narrative progress report is required to be submitted by the grantee on behalf of all affiliated institutions to the Division of Regional Medical Programs for each budget period of the program period. If the grantee fails to submit an expenditures report within 120 days after the end of each budget period, future awards for that activity may be withheld.

A supplemental grant forms a part of the existing grant and only one expenditure report need be submitted on the combined grants.

(2) Time or Effort Report—Charges for salaries and wages of individuals other than members of the professional staff will be supported by time and attendance and payroll distribution records. For members of the professional staff, quarterly estimates of the percentage distribution of their total effort must be used as support in the absence of actual time records. Time and effort reports are not to be sent to the Division of Regional Medical Programs but must be retained by the grantee and must be made available for inspection by the Public Health Service staff.

Miscellaneous—

(1) Safety Precautions—The Public Health Service assumes no responsibility with respect to accident, claims or illness arising out of any work undertaken with the assistance of a Public Health Service grant. The grantee institution is expected to take necessary steps to insure or protect itself and its personnel.

(2) Federal Income Tax—Determination of a tax status of an individual receiving compensation in any form from the Public Health Service grant is the responsibility of the Internal Revenue Service.

(3) Military Service—The Public Health Service will not intercede on behalf of an individual in relation to military status.

Chapter IV

PREPARATION AND REVIEW OF APPLICATIONS

I. Types of Applications

A. New Applications

New applications are submitted by Regional Medical Programs for initial planning grants or initial operational grants.

B. Supplemental Applications

The supplemental application requests funds for a specific grant period for the expansion of activities already funded and/or the addition of new activities. The supplemental application may request expansion of central functions of the Regional Medical Program, such as coordinating, planning, evaluation, and for administrative staff. The application may request funding for new operational projects for incorporation into the Regional Medical Program. Supplemental applications may be submitted at any time during the specific period of the grant they are to supplement.

C. Continuation Applications

This application requests support for an additional budget period included in the program period specified in the current statement or award.

D. Renewal Applications

This application requests support for an extension of a Regional Medical Program beyond the program period.

E. Applications for Revision

These are applications which propose substantial program modification in already funded projects or activities.

II. General Format For All Applications

A. Form

Application form NIH-925-1 (Revised May 1966) is used for all grant applications and may be obtained on request from the Grants Review Branch, Division of Regional Medical Programs, National Institutes of Health, Bethesda, Maryland

20014. Specific instructions for completion accompany the form.

B. Budget

A specific justification of the budget estimate must be supplied and must include enough specific information to support the actual amount of funds requested. Allowable budget costs are described in Chapter III. The presentation of the budget and its justification should be clear and well organized, and the computations carefully checked for accuracy. In all requests for support beyond one year, the budget is presented in two parts—the detailed presentation of the amounts requested for the first budget period (usually twelve months) and an estimated projection of funds needed for each of the subsequent budget periods for which a commitment of support is requested. The projections should be estimated as realistically as possible on the basis of the first year level less non-recurring costs, such as fixed equipment and renovation and alteration costs. Increases to provide for program expansion, regular salary increments and phasing of projects should be fully explained. The budget for the initial year of a project should make realistic allowance for anticipated delays in recruiting staff for the project.

C. Narrative

The body of each application will consist of a narrative, which provides the full justification for the request and relates the proposal to the objectives of the Regional Medical Program.

D. Supporting Documents

Applications will include necessary supporting documents, such as statutory or regulatory assurances, curricula vitae of the persons involved, and other supplementary information.

III. Specific Format

A. Planning Application

The planning grant application should include

a narrative justification for the proposed Region including appropriate demographic and descriptive data which support the preliminary delineation of the Region, background and history of the proposed Regional Medical Program, including a description of relationships of adjacent Regions, descriptions of the proposed organizational structure and how it will function, the nature of the Regional Advisory Group and how it was selected, and a description of how the planning activities will contribute to the goal of the Regional Medical Program in terms of the seven elements of the process of regionalization described in Chapter II.

B. Planning Supplemental Application

The narrative in this application should include a description of planning progress to date, why currently available planning funds are insufficient, and a description of the expanded planning activities which would result from the supplemental funding being requested. This application should be accompanied by current budget information about the ongoing grant which gives expenditures to date and projected expenditures to the end of the budget period and which supports the need for additional funding.

C. New Operational Grant

An application for an operational grant must include notification of the approval of the Regional Advisory Group as required by the Act. This notification must bear an original signature of the chairman and should be placed prominently in the application. Assurances such as those having to do with civil rights, human experimentation, and other assurances not already on file with the Division should be attached as appendices and will be maintained on file by the Division of Regional Medical Programs. The narrative of the operational grant application should cover the following general points:

1. A restatement of the justification of the region and description of redelineation, if pertinent, for accomplishing the purposes of the operational Regional Medical Program.

2. Accomplishments under the program supported by the planning grant and the specific results of the planning process that led to the development and submission of the operational request.

3. A complete discussion of the conceptual strategy for carrying out the process of regionalization directed toward the goal of improved patient care as described in Chapter II. This description

must include the relationship of the proposed operational program to the continued planning activities and, to the extent possible, in the context of the specific elements described in Chapter II.

4. A description of Program organization, staffing, leadership capability, and decision-making mechanisms should be included.

In addition to these general considerations, the applications for operational grants should include descriptions of the individual projects. The general narrative should provide the basis for relating the specific projects to the overall development of the Program and should enable the review groups to reach the conclusion that the Program has a unified strategy and is not a group of unrelated projects. Separate budgets should be included for each project with a budget justification and where appropriate an identification of the planning group or subcommittee within the Regional Medical Program that may have participated in developing the particular project. The narrative description for the project should cover:

1. Justification of the contribution to the overall Regional Medical Program

2. Relationship to planning and to other operational projects already undertaken, as well as continued planning and operational activities

3. The anticipated rate of implementation of the project

4. The contribution of the individual project to the process of regionalization described in Chapter II

5. Supporting documents for each project, such as curricula vitae of principal staff members, project directors, their leading assistants. These should be brief and the list of publications should be limited to the past five years.

D. Supplemental Operational Application

This application requests expansion of the activities or projects already funded under the operational grant or proposals for other projects integrated into the Regional Medical Program. The supplemental application needs to relate the proposed additional activities or expansion to the general development of the Regional Medical Program as described in the narrative for the initial operational application. The supplemental application should summarize for the reviewers the developments in the Regional Medical Program since previous applications or progress reports were submitted to the Division. The detail of this summary will depend upon the time which has

elapsed since such information was previously supplied to the Division. Projects proposed in the supplemental application should be described in the same terms that are outlined above (see C). Any additional assurances required because of new activities proposed should be included along with the documentation of the approval of the Regional Advisory Group including the original signature of the chairman.

E. Continuation Application

Application for continuation of Programs beyond the current budget period into budget periods for which support was committed in the original grant award must be submitted not less than thirty days prior to the end of each budget year within the approved program period. Detailed instructions for completion of the continuation application will be supplied to the grantee by the Division staff approximately three months prior to expiration of the budget period. Such an application will include:

1. The progress report (see Chapter III)
2. The required annual report of the Regional Advisory Group (see Chapter III)
3. An Annual Invention Statement
4. An estimated Statement of Expenditures (NIH 925-3) for the current year based on the total budget as set forth in the current Notice of Grant Awarded (NIH 925-2) and on each project included within an operational grant.

Funds remaining from a specific grant period may not be used unless:

1. They are justified as a part of the budget of the continuation grant application, and
2. The expansion of the Program beyond the original commitment of funds is clearly justified in terms of its relevance to the program areas funded in the original grant. Such a request will frequently require approval by the National Advisory Council.

F. Application for Renewal Grant

A renewal application must be submitted for continued support beyond the completion of the committed program period. These applications are essentially identical to new applications except that the narrative must include a summary of the progress made during the entire previous program period and an assessment of the status of the Regional Medical Program at the time of the application.

G. Application for Revision

Applications for revisions request permission to use already awarded grant funds for activities or projects which are substantially different from those presented in the application upon which the award was based. The limitations on budget revisions are discussed in Chapter III. Any substantial revision in a Program approach or project content whether or not they require budget revisions requires written approval of the Division of Regional Medical Programs and must be discussed with the Division. If a substantial change is proposed, it should be presented in the format of a supplemental application.

IV. Application Procedure

A. Schedule

Applications to the Division of Regional Medical Programs may be submitted at any time. A date set approximately six weeks prior to each meeting of the Regional Medical Program Review Committee is set as the limit for receipt of applications for the review cycle initiated by that meeting. There are usually four such cycles each year. A calendar of these dates and the dates of all Review Committee and the National Advisory Council meetings is kept current for at least one full year in advance and distributed regularly to all program coordinators.

B. Number of Copies

Applicants are requested to submit twenty copies of an application.

C. Style

Applicants should adopt a typographic style which will permit stapling or binding in a three-ring binder. Each page should be suitable for photographic reproduction. The narrative should be typed single spaced to conserve space.

V. Review Process

As had been described earlier, each region develops for itself a regional advisory group whose review and approval of projects contained in operational applications is required by statute. For other types of applications, while endorsement by the regional advisory group is not a statutory necessity, its inclusion in the application is highly recommended as evidence of the effective involvement of this group.

A. Receipt of Application

When the application is received by the Division

of Regional Medical Programs, an initial review for accuracy and compliance with regulations and policies is undertaken. Copies are routinely sent to designated liaison personnel in the related categorical institutes of the National Institutes of Health and to other bureaus of the Public Health Service. In the case of operational applications, individual projects are referred for specific technical evaluation to other program elements within the Service and in other agencies.

B. Review by Regional Medical Program Review Committee

Review by this multidisciplinary group constitutes the initial review of the application. Review Committee meetings are scheduled regularly to review and evaluate the professional aspects of all Regional Medical Program applications, consider reports of staff, outside reviewers and site visit teams, and recommend time and amount of support to Council for its consideration at a subsequent meeting. The Review Committee participates in site visits to Regions which are made frequently in the case of planning applications and routinely for operational applications. In the more complex operational applications, the review cycle may not be complete until a second review by the Committee has taken place. This may be occasioned by problems raised by technical reviewers, overlap with other programs, feasibility of proposals and other relevant program considerations.

C. Site Visits

Site visits are made routinely in the case of operational applications and as determined by the Committee or Council for other applications. The purpose is to permit a personal in-depth presentation of the applicant's proposals to a group of disinterested consultants. A site visit team is usually made up of members of the National Advisory Council, the Review Committee, staff representa-

tives and consultants who represent specialized competencies. Site visits are arranged from four to six weeks in advance by staff of the Division of Regional Medical Programs. In the case of operational applications, the visits require from one to two days. At the conclusion of the visit, the site visit team draws up a report which is presented at the next Review Committee meeting or to the National Advisory Council.

D. Review by National Advisory Council

The final review of applications is by the National Advisory Council. The Council considers the recommendations and findings of the Review Committee including the full array of material assembled during the entire review process. The Council's final recommendation, required by the law before a grant can be awarded, concerns the application as a whole and includes a recommendation of the overall grant amount. Where still further exchange of information is considered necessary to resolve major questions, a further Council site visit may be arranged.

E. Approval and Award

After the Council's recommendations are made, Division of Regional Medical Program staff meet representatives of the applicant Region, and relate the Council's concerns and recommendations in detail. The applicant will be informed if certain proposed projects have been specifically disapproved. If the recommended amount has been reduced below the amount requested for those projects or activities not specifically disapproved, the applicant has the opportunity to return to its own decision-making group, to reassess priorities, and to submit a budget which redistributes the recommended amount among its approved projects or component activities. It is on the basis of this re-submitted budget with the projects it covers that a grant is made and that the program for the budget period is set.

GLOSSARY

- 1. Act (Public Law 89-239 or Title IX)**
is the Heart Disease Cancer, and Stroke amendments of 1965 to the Public Health Service Act.
- 2. Affiliated Agency (See Agency)**
- 3. Agency (Institution)**
 - Cooperating**
is an agency (institution) which has indicated its willingness to cooperate in a Regional Medical Program.
 - Affiliated**
is a cooperative agency (institution) which is the recipient of Title IX grant funds from the grantee. (This does not include profit making organizations or payment made for the use of facilities or services rendered.)
- 4. Agreement of Affiliation**
is the written agreement between the grantee and each affiliated agency which assures both the grantee and the Public Health Service that funds awarded under the Act will be used in accordance with Public Health Service policies and procedures.
- 5. Applicant**
is the public or nonprofit corporate organization or institution which submits a request for funds under the Act and which proposes to become the grantee.
- 6. Approved Program**
is comprised of the activities which the applicant has submitted to the Federal Government for funding and which have been recommended to the Surgeon General for approved by the National Advisory Council on Regional Medical Programs.
- 7. Budget Period**
is the period of time covered by a specific budget, usually twelve months.
- 8. Clinical Research Center**
is an institution (or part of an institution) the primary function of which is research, training of specialists, and demonstrations; and which, in connection therewith, provides specialized, high-quality diagnostic and treatment services for inpatients and outpatients.
- 9. Construction**
is alteration, major repair (including the restoration of an existing building to a sound state), and renovation of existing buildings (including initial equipment thereof) and replacement of obsolete, built-in equipment (equipment affixed to the facility and customarily included in the construction contract) of existing buildings.
- 10. Continuation Grant (See Grant)**
- 11. Cooperating Agency (See Agency)**
- 12. Division of Regional Medical Programs**
is the Division of the National Institutes of Health which is principally responsible for the administration of the Act.
- 13. Feasibility Studies**
are those activities, supported as a portion of a planning grant, the principal purpose of which is aimed at assessing the workability and utility of particular program elements.
- 14. Grant**
 - Planning**
is a grant authorized by Section 903 of the Act which is made to assist in the planning and development of a Regional Medical Program.
 - Operational**
is a grant authorized by Section 904 of the Act which is made to assist in the establishment or operation of a Regional Medical Program.
 - Supplemental**
is a grant which provides support for expansion of existing, previously funded, or new program elements.
 - Continuation**
is a grant which provides support for an additional budget period included in the program period specified in the current statement of award.

Renewal

is a grant which provides for the extension of a Regional Medical Program beyond the program period.

15. Grantee

is the public or nonprofit institution, agency or corporation which is the recipient of grant funds under the Act.

16. Hospital

is a general, tuberculosis, or other type of hospital and related facility, such as a laboratory, outpatient department, (nurses' home facility) and central service facility operated in connection with hospitals or other health facilities in which local capability for diagnosis and treatment is supported and augmented by the program established under the Act, but does not include any hospital furnishing primarily domiciliary care.

17. Institution (See Agency)**18. Maintenance of Effort**

is the principle, which applies to Federal funds paid pursuant to any operational grant, requiring that grant funds will *not* supplant funds that are otherwise available for establishment or operation of the Regional Medical Program.

19. Medical Center

is a medical school or other medical institution involved in postgraduate medical training and one or more hospitals affiliated therewith for teaching, research, and demonstration purposes.

20. National Advisory Council on Regional Medical Programs

is the body authorized by Section 905 of the Act which shall advise and assist the Surgeon General in the preparation of regulations for, and as to policy matters arising with respect to, the administration of the Act. The Council shall be comprised of the Surgeon General, who shall be the chairman, and twelve members who are leaders in the fields of the fundamental sciences, the medical sciences, or public affairs. At least two shall be practicing physicians, one shall be outstanding in the study, diagnosis, or treatment of heart disease;

one shall be outstanding in the study, diagnosis, or treatment of cancer; and one shall be outstanding in the study, diagnosis, or treatment of stroke. The Council shall consider all applications for grants under the Act and shall make recommendations to the Surgeon General with respect to approval of applications for and amounts of grants under the Act.

21. Nonprofit Status

is any institution or agency which is owned and operated by one or more nonprofit corporations or associations no part of the net earning of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

22. Operational Grant (See Grant)**23. Planning Grant (See Grant)****24. Practicing Physician**

is any physician licensed to practice medicine in accordance with applicable state laws and currently engaged in the diagnosis and treatment of patients.

25. Program Coordinator

is the person who bears the principal administrative responsibility for the overall coordination of the Regional Medical Program.

26. Program Period

is the period of time for which new and/or continuing support under the Act has been recommended by the National Advisory Council on Regional Medical Programs, not exceeding five years.

27. Progress Report

is the annual report submitted to the Division of Regional Medical Programs by the grantee which describes the progress, accomplishments and problems of the Regional Medical Program.

28. Project

is a particular activity which is undertaken by the Regional Medical Program as an integral part of its overall operational program.

29. Region

is a geographically and/or functionally defined area which the Surgeon General deter-

mines forms an economic and socially related region, taking into consideration such factors as present and future population trends and patterns of growth; location and extent of transportation and communication facilities and systems; and presence and distribution of educational, medical, and health facilities and programs.

30. Regional Advisory Group

is the group designated by the applicant (and the institutions cooperating in the Regional Medical Program) to advise them concerning the establishment and operation of their Regional Medical Program. Such groups shall consist of practicing physicians, medical center officials, hospital administrators, representatives from appropriate medical societies, voluntary health agencies, and representatives of other agencies, organizations, and institutions concerned with activities of the kind to be carried out under the Program, and members of the public familiar with the need for the services provided under the Program.

31. Regional Cooperative Arrangement
(See Regionalization)

32. Regional Medical Program

is the cooperative arrangement among the health resources of a region the purpose of which is to make available to all those persons within the region the best possible patient care for heart disease, cancer, stroke and related diseases through research, training, and demonstration of patient care.

33. Regionalization (Regional Cooperative Arrangement)

is the process whereby the region moves toward its goal of improved patient care for

those suffering from heart disease, cancer, stroke, or related diseases.

34. Related Diseases

are those diseases which can reasonably be considered to bear a direct relationship to heart disease, cancer, or stroke.

35. Renewal Grant (See Grant)

36. Report

is the Surgeon General's Report on Regional Medical Programs to the President and the Congress required by Section 908 of the Act.

37. Review Committee

is a formally established Public Health Service review committee which performs the initial review of grant requests under the Act.

38. Site Visit

is an official visit to a Region by persons from either or both the National Advisory Council on Regional Medical Programs and the Review Committee the principal purposes of which are to make judgments concerning proposed or ongoing activities of the Regional Medical Program and to enable both the site visitors and the Region to better understand Regional Medical Programs.

39. Supplemental Grant (See Grant)

40. Surgeon General

is the Surgeon General of the Public Health Service.

41. Title IX (See Act)

42. Unexpended Balance

is the balance of funds remaining in the grant account at the end of each budget period.

APPENDIX 1

PUBLIC LAW 89-239
89TH CONGRESS, S. 596
OCTOBER 6, 1965
AN ACT

Heart Disease, Cancer, and Stroke Amendments of 1965

To amend the Public Health Service Act to assist in combating heart disease, cancer, stroke, and related diseases.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Heart Disease, Cancer, and Stroke Amendments of 1965."

SEC. 2. The Public Health Service Act (42 U.S.C., ch. 6A) is amended by adding at the end thereof the following new title:

"TITLE IX—EDUCATION, RESEARCH, TRAINING, AND DEMONSTRATIONS IN THE FIELDS OF HEART DISEASE, CANCER, STROKE, AND RELATED DISEASES"

"Purposes"

"SEC. 900. The purposes of this title are—

"(a) Through grants, to encourage and assist in the establishment of regional cooperative arrangements among medical schools, research institutions, and hospitals for research and training (including continuing education) and for related demonstrations of patient care in the fields of heart disease, cancer, stroke, and related diseases:

"(b) To afford to the medical profession and the medical institutions of the Nation, through such cooperative arrangements, the opportunity of making available to their patients the latest advances in the diagnosis and treatment of these diseases; and

"(c) By these means, to improve generally the health manpower and facilities available to the Nation, and to accomplish these ends without interfering with the patterns, or the methods of financing, of patient care or professional practice, or with the administration of hospitals, and in cooperation with practicing physicians, medical center officials, hospital administrators, and representatives from appropriate voluntary health agencies.

"Authorization of Appropriations"

"SEC. 901. (a) There are authorized to be appropriated \$50,000,000 for the fiscal year ending June 30, 1966, \$90,000,000 for the fiscal year ending June 30, 1967, and \$200,000,000, for the fiscal year ending June 30, 1968, for grants to assist public or non-profit private universities, medical schools, research institutions, and other public or nonprofit private institutions and agencies in planning, in conducting feasibility studies, and in operating pilot projects for the establishment of regional medical programs of research, training, and demonstration activities for carrying out the purposes of this title. Sums appropriated under this section for any fiscal year shall remain available for making such grants until the end of the fiscal year following the fiscal year for which the appropriation is made.

"(b) A grant under this title shall be for part or all of the cost of the planning or other activities with respect to which the application is made, except that any such grant with respect to construction of, or provision of built-in (as determined in accordance with regulations) equipment for, any facility may not exceed 90 per centum of the cost of such construction or equipment.

"(c) Funds appropriated pursuant to this title shall not be available to pay the cost of hospital, medical, or other care of patients except to the extent it is, as determined in accordance with regulations, incident to those research, training, or demonstration activities which are encompassed by the purposes of this title. No patient shall be furnished hospital, medical, or other care at any facility incident to research, training, or demonstration activities carried out with funds appropriated pursuant to this title, unless he has been referred to such facility by a practicing physician.

"Definitions"

"SEC. 902. For the purposes of this title—

"(a) The term 'regional medical program' means a cooperative arrangement among a group of public or nonprofit private institutions or agencies engaged in research, training, diagnosis, and treatment relating to heart disease, cancer, or stroke, and, at the option of the applicant, related disease or diseases; but only if such group—

"(1) is situated within a geographic area, composed of any part or parts of any one or more States, which the Surgeon General determines, in accordance with regulations, to be appropriate for carrying out the purposes of this title;

"(2) consists of one or more medical centers, one or more clinical research centers, and one or more hospitals; and

"(3) has in effect cooperative arrangements among its component units which the Surgeon General finds will be adequate for effectively carrying out the purposes of this title.

"(b) The term 'medical center' means a medical school or other medical institution involved in postgraduate medical training and one or more hospitals affiliated therewith for teaching, research, and demonstration purposes.

"(c) The term 'clinical research center' means an institution (or part of an institution) the primary function of which is research, training of specialists, and demonstrations and which, in connection therewith, provides specialized, high-quality diagnostic and treatment services for inpatients and outpatients.

"(d) The term 'hospital' means a hospital as defined in section 625 (c) or other health facility in which local capability for diagnosis and treatment is supported and augmented by the program established under this title.

"(e) The term 'nonprofit' as applied to any institution or agency means an institution or agency which is owned and operated by one or more nonprofit corporations or associations no part of the net earnings of which inures, or may

lawfully inure, to the benefit of any private shareholder or individual.

"(f) The term 'construction' includes alteration, major repair (to the extent permitted by regulations), remodeling and renovation of existing buildings (including initial equipment thereof), and replacement of obsolete, built-in (as determined in accordance with regulations) equipment of existing building.

"Grants for Planning

"SEC. 903. (a) The Surgeon General, upon the recommendation of the National Advisory Council on Regional Medical Programs established by section 903 (hereafter in this title referred to as the 'Council'), is authorized to make grants to public or nonprofit private universities, medical schools, research institutions, and other public or nonprofit private agencies and institutions to assist them in planning the development of regional medical programs.

"(b) Grants under this section may be made only upon application therefor approved by the Surgeon General. Any such application may be approved only if it contains or is supported by—

"(1) reasonable assurances that Federal funds paid pursuant to any such grant will be used only for the purposes for which paid and in accordance with the applicable provisions of this title and the regulations thereunder;

"(2) reasonable assurances that the applicant will provide for such fiscal control and fund accounting procedures as are required by the Surgeon General to assure proper disbursement of and accounting for such Federal funds;

"(3) reasonable assurances that the applicant will make such reports, in such form and containing such information as the Surgeon General may from time to time reasonably require, and will keep such records and afford such access thereto as the Surgeon General may find necessary to assure the correctness and verification of such reports; and

"(4) a satisfactory showing that the applicant has designated an advisory group, to advise the applicant (and the institutions and agencies participating in the resulting regional medical program) in formulating and carrying out the plan for the establishment and operation of such regional medical program, which advisory group includes practicing physicians, medical center officials, hospital administrators, representatives from appropriate medical societies, voluntary health agencies, and representatives of other organizations, institutions, and agencies concerned with activities of the kind to be carried on under the program and members of the public familiar with the need for the services provided under the program.

"Grants for Establishment and Operation of Regional Medical Programs

"SEC. 904. (a) The Surgeon General, upon the recommendation of the Council, is authorized to make grants to public or nonprofit private universities, medical schools, research institutions, and other public or nonprofit private agencies and institutions to assist in establishment and operation of regional medical programs, including construction and equipment of facilities in connection therewith.

"(b) Grants under this section may be made only upon application therefor approved by the Surgeon General. Any

such application may be approved only if it is recommended by the advisory group described in section 903 (b) (4) and contains or is supported by reasonable assurances that—

"(1) Federal funds paid pursuant to any such grant

(A) will be used only for the purposes for which paid and in accordance with the applicable provisions of this title and the regulations thereunder, and (B) will not supplant funds that are otherwise available for establishments or operation of the regional medical program with respect to which the grant is made;

"(2) the applicant will provide for such fiscal control and fund accounting procedures as are required by the Surgeon General to assure proper disbursement of and accounting for such Federal funds;

"(3) the applicant will make such reports, in such form and containing such information as the Surgeon General may from time to time reasonably require, and will keep such records and afford such access thereto as the Surgeon General may find necessary to assure the correctness and verification of such reports; and

"(4) any laborer or mechanic employed by any contractor or subcontractor in the performance of work on any construction aided by payments pursuant to any grant under this section will be paid wages at rates not less than those prevailing on similar construction in the locality as determined by the Secretary of Labor in accordance with the Davis-Bacon Act, as amended (40 U.S.C. 276a-5); and the Secretary of Labor shall have, with respect to the labor standards specified in this paragraph, the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (15 F.R. 3176; 5 U.S.C. 133z-15) and section 2 of the Act of June 13, 1934, as amended (40 U.S.C. 276c).

"National Advisory Council on Regional Medical Programs

Appointment of members.

"SEC. 905. (a) The Surgeon General, with the approval of the Secretary, may appoint, without regard to the civil service laws, a National Advisory Council on Regional Medical Programs. The Council shall consist of the Surgeon General, who shall be the chairman, and twelve members, not otherwise in the regular full-time employ of the United States, who are leaders in the fields of the fundamental sciences, the medical sciences, or public affairs. At least two of the appointed members shall be practicing physicians, one shall be outstanding in the study, diagnosis, or treatment of heart disease, one shall be outstanding in the study, diagnosis, or treatment of cancer, and one shall be outstanding in the study, diagnosis, or treatment of stroke.

Term of office.

"(b) Each appointed member of the Council shall hold office for a term of four years, except that any member appointed to fill a vacancy prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term, and except that the terms of office of the members first taking office shall expire, as designated by the Surgeon General at the time of appointment, four at the end of the first year, four at the end of the second year, and four at the end of the third year after the date of appointment. An appointed member shall not be eligible to serve continuously for more than two terms.

Compensation.

"(c) Appointed members of the Council, while attending

meetings or conferences thereof or otherwise serving on business of the Council, shall be entitled to receive compensation at rates fixed by the Secretary, but not exceeding \$100 per day, including traveltime, and while so serving away from their homes or regular places of business they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5 of the Administrative Expenses Act of 1946 (5 U.S.C. 73b-2) for persons in the Government service employed intermittently.

Application for grants, recommendations.

"(d) The Council shall advise and assist the Surgeon General in the preparation of regulations for, and as to policy matters arising with respect to, the administration of this title. The Council shall consider all applications for grants under this title and shall make recommendations to the Surgeon General with respect to approval of applications for and the amount of grants under this title.

"Regulations

"SEC. 906. The Surgeon General, after consultation with the Council, shall prescribe general regulations covering the terms and conditions for approving applications for grants under this title and the coordination of programs assisted under this title with programs for training, research, and demonstrations relating to the same diseases assisted or authorized under other titles of this Act or other Acts of Congress.

"Information on Special Treatment and Training Centers

"SEC. 907. The Surgeon General shall establish, and maintain on a current basis, a list or lists of facilities in the United States equipped and staffed to provide the most advanced methods and techniques in the diagnosis and treatment of heart disease, cancer, or stroke, together with such related information, including the availability of advanced specialty training in such facilities, as he deems useful, and shall make such list or lists and related information readily available to licensed practitioners and other persons requiring such information. To the end of making such list or lists and other information most useful, the Surgeon General shall from time to time consult with interested national professional organizations.

Report to President and Congress

"SEC. 908. On or before June 30, 1967, the Surgeon General after consultation with the Council, shall submit to the Secretary for transmission to the President and then to the

Congress, a report of the activities under this title together with (1) a statement of the relationship between Federal financing and financing from other sources of the activities undertaken pursuant to this title, (2) an appraisal of the activities assisted under this title in the light of their effectiveness in carrying out the purposes of this title, and (3) recommendations with respect to extension or modification of this title in the light thereof.

"Records and Audit

"SEC. 909. (a) Each recipient of a grant under this title shall keep such records as the Surgeon General may prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, to total cost of the project or undertaking in connection with which such grant is made or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such records as will facilitate an effective audit.

"(b) The Secretary of Health, Education, and Welfare and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of any grant under this title which are pertinent to any such grant."

"SEC. 3. (a) Section 1 of the Public Health Service Act is amended to read as follows:

"SECTION 1. Titles I to IX, inclusive, of this Act may be cited as the 'Public Health Service Act'."

(b) The Act of July 1, 1944 (58 Stat. 682), as amended, is further amended by renumbering title IX (as in effect prior to the enactment of this Act) as title X, and by renumbering sections 901 through 914 (as in effect prior to the enactment of this Act), and references thereto, as sections 1001 through 1014, respectively.

APPROVED OCTOBER 6, 1965, 10:15 A.M.

Legislative History:

House Report No. 963 accompanying H.R. 3140 (Comm. on Interstate and Foreign Commerce).

Senate Report No. 368 (Comm. on Labor and Public Welfare).

Congressional Record, Vol. 111 (1965):

June 25: Considered in Senate.

June 28: Considered and passed Senate.

Sept. 23: H. R. 3140 considered in House.

Sept. 24: Considered and passed House, amended, in lieu of H.R. 3140.

Sept. 29: Senate concurred in House amendments.

APPENDIX 2

REGULATIONS REGIONAL MEDICAL PROGRAMS MARCH 18, 1967

SUBPART E—GRANTS FOR REGIONAL MEDICAL PROGRAMS

(Added 1/18/67, 32 FR 571.)

AUTHORITY: The provisions of this Subpart E issued under sec. 215, 58 Stat. 690, sec. 906, 79 Stat. 930; 42 U.S.C. 216, 299f, Interpret or apply secs. 900, 901, 902, 903, 904, 905, 909, 79 Stat. 926, 927, 928, 929, 930, 42 U.S.C. 299, 299a, 299b, 299c, 299d, 299e, 299i.

☐ 54.401 APPLICABILITY.

The provisions of this subpart apply to grants for planning, establishment, and operation of regional medical programs as authorized by Title IX of the Public Health Service Act, as amended by Public Law 89-239.

☐ 54.402 DEFINITIONS.

(a) All terms not defined herein shall have the meaning given them in the Act.

(b) "Act" means the Public Health Service Act, as amended.

(c) "Title IX" means Title IX of the Public Health Service Act as amended.

(d) "Related diseases" means those diseases which can reasonably be considered to bear a direct relationship to heart disease, cancer, or stroke.

(e) "Title IX diseases" means heart disease, cancer, stroke, and related diseases.

(f) "Program" means the regional medical program as defined in section 902 (a) of the Act.

(g) "Practicing physician" means any physician licensed to practice medicine in accordance with applicable State laws and currently engaged in the diagnosis or treatment of patients.

(h) "Major repair" includes restoration of an existing building to a sound state.

(i) "Built-in equipment" is equipment affixed to the facility and customarily included in the construction contract.

(j) "Advisory group" means the group designated pursuant to section 903 (b) (4) of the Act.

(k) "Geographic area" means any area that the Surgeon General determines forms an economic and socially related region, taking into consideration such factors as present and future population trends and patterns of growth; location and extent of transportation and communication facilities and systems; presence and distribution of educational, medical and health facilities and programs, and other activities which in the opinion of the Surgeon General are appropriate for carrying out the purposes of Title IX.

☐ 54.403 ELIGIBILITY.

In order to be eligible for a grant, the applicant shall:

(a) Meet the requirements of section 903 or 904 of the Act;

(b) Be located in a State;

(c) Be situated within a geographic area appropriate under the provisions of this subpart for carrying out the purposes of the Act.

☐ 54.404 APPLICATION.

(a) *Forms.* An application for a grant shall be submitted on such forms and in such manner as the Surgeon General may prescribe.

(b) *Execution.* The application shall be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant all of the obligations specified in the terms and conditions of the grant including those contained in these regulations.

(c) *Description of program.* In addition to any other pertinent information that the Surgeon General may require, the applicant shall submit a description of the program in sufficient detail to clearly identify the nature, need, purpose, plan, and methods of the program, the nature and functions of the participating institutions, the geographic area to be served, the cooperative arrangements in effect, or intended to be made effective, within the group, the justification supported by a budget or other data, for the amount of the funds requested, and financial or other data demonstrating that grant funds will not supplant funds otherwise available for establishment or operation of the regional medical program.

(d) *Advisory group; establishment; evidence.* An application for a grant under section 903 of the Act shall contain or be supported by documentary evidence of the establishment of an advisory group to provide advice in formulating and carrying out the establishment and operation of a program.

(e) *Advisory group; membership; description.* The application or supporting material shall describe the selection and membership of the designated advisory group, showing the extent of inclusion in such group of practicing physicians, members of other health professions, medical center officials, hospital administrators, representatives from appropriate medical societies, voluntary agencies, representatives of other organizations, institutions and agencies concerned with activities of the kind to be carried on under the program, and members of the public familiar with the need for the services provided under the program.

(f) *Construction; purpose, plans, and specifications; narrative description.* With respect to an application for funds to be used in whole or part for construction as defined in Title IX, the applicant shall furnish in sufficient detail plans and specifications as well as a narrative description, to indicate the need, nature, and purpose of the proposed construction.

(g) *Advisory group; recommendation.* An application for a grant under section 904 of the Act shall contain or be supported by a copy of the written recommendation of the advisory group.

☐ 54.405 TERMS, CONDITIONS,
AND ASSURANCES.

In addition to any other terms, conditions, and assurances required by law or imposed by the Surgeon General, each grant shall be subject to the following terms, conditions, and assurances to be furnished by the grantee. The Surgeon General may at any time approve exceptions where he finds that such exceptions are not inconsistent with the Act and the purposes of the program.

(a) *Use of funds.* The grantee will use grant funds solely for the purposes for which the grant was made, as set forth in the approved application and award statement. In the event any part of the amount paid a grantee is found by the Surgeon General to have been expended for purposes or by any methods contrary to the Act, the regulations of this subpart, or contrary to any condition to the award, then such grantee, upon being notified of such finding, and in addition to any other requirement, shall pay an equal amount to the United States. Changes in grant purposes may be made only in accordance with procedures established by the Surgeon General.

(b) *Obligation of funds.* No funds may be charged against the grant for services performed or material or equipment delivered, pursuant to a contract or agreement entered into by the applicant prior to the effective date of the grant.

(c) *Inventions or discoveries.* Any grant award hereunder in whole or in part for research is subject to the regulations of the Department of Health, Education, and Welfare as set forth in Parts 6 and 8 of Title 45, as amended. Such regulations shall apply to any program activity for which grant funds are in fact used whether within the scope of the program as approved or otherwise. Appropriate measures shall be taken by the grantee and by the Surgeon General to assure that no contracts, assignments, or other arrangements inconsistent with the grant obligation are continued or entered into and that all personnel involved in the supported activity are aware of and comply with such obligation. Laboratory notes, related technical data, and information pertaining to inventions or discoveries made through activities supported by grant funds shall be maintained for such periods, and filed with or otherwise made available to the Surgeon General or those he may designate at such times and in such manner as he may determine necessary to carry out such Department regulations.

(d) *Reports.* The grantee shall maintain and file with the Surgeon General such progress, fiscal, and other reports, including reports of meetings of the advisory group convened before and after award of a grant under section 904 of the Act, as the Surgeon General may prescribe.

(e) *Records retention.* All construction, financial, and other records relating to the use of grant funds shall be retained until the grantee has received written notice that the records have been audited unless a different period is permitted or required in writing by the Surgeon General.

(f) *Responsible official.* The official designated in the application as responsible for the coordination of the program shall continue to be responsible for the duration of the period for which grant funds are made available. The grantee shall notify the Surgeon General immediately if such official becomes unavailable to discharge this responsibility. The Surgeon General may terminate the grant whenever such official shall become thus unavailable unless the grantee

replaces such official with another official found by the Surgeon General to be qualified.

☐ 54.406 AWARD.

Upon recommendation of the National Advisory Council on Regional Medical Programs, and within the limits of available funds, the Surgeon General shall award a grant to those applicants whose approved programs will in his judgment best promote the purposes of Title IX. In awarding grants, the Surgeon General shall take into consideration, among other relevant factors the following:

(a) Generally, the extent to which the proposed program will carry out, through regional cooperation, the purposes of Title IX, within a geographic area.

(b) The capacity of the institutions or agencies within the program, individually and collectively, for research, training, and demonstration activities with respect to Title IX.

(c) The extent to which the applicant or the participants in the program plan to coordinate or have coordinated the regional medical program with other activities supported pursuant to the authority contained in the Public Health Service Act and other Acts of Congress including those relating to planning and use of facilities, personnel, and equipment, and training of manpower.

(d) The population to be served by the regional medical program and relationships to adjacent or other regional medical programs.

(e) The extent to which all the health resources of the region have been taken into consideration in the planning and/or establishment of the program.

(f) The extent to which the participating institutions will utilize existing resources and will continue to seek additional nonfederal resources for carrying out the objectives of the regional medical program.

(g) The geographic distribution of grants throughout the Nation.

☐ 54.407 TERMINATION.

(a) *Termination by the Surgeon General.* Any grant award may be revoked or terminated by the Surgeon General in whole or in part at any time whenever he finds that in his judgment the grantee has failed in a material respect to comply with requirements of Title IX and the regulations of this subpart. The grantee shall be promptly notified of such finding in writing and given the reasons therefor.

(b) *Termination by the grantee.* A grantee may at any time terminate or cancel its conduct of an approved project by notifying the Surgeon General in writing setting forth the reasons for such termination.

(c) *Accounting.* Upon any termination, the grantee shall account for all expenditures and obligations charged to grant funds: *Provided,* That to the extent the termination is due in the judgment of the Surgeon General to no fault of the grantee, credit shall be allowed for the amount required to settle at costs demonstrated by evidence satisfactory to the Surgeon General to be minimum settlement costs, any non-cancellable obligations incurred prior to receipt of notice of termination.

☐ 54.408 NONDISCRIMINATION.

Section 601 of Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d, provides that no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be

subjected to discrimination under any program or activity receiving Federal financial assistance. Regulations implementing the statute have been issued as Part 80 of the Title 45, Code of Federal Regulations. The regional medical programs provide Federal financial assistance subject to the Civil Rights Act and the regulations. Each grant is subject to the condition that the grantee shall comply with the requirements of Executive Order 11246, 30 F.R. 12319, and the applicable rules, regulations, and procedures prescribed pursuant thereto.

☐ 54.409 EXPENDITURES BY GRANTEE.

(a) *Allocation of costs.* The grantee shall allocate expenditures as between direct and indirect costs in accordance with generally accepted and established accounting practices or as otherwise prescribed by the Surgeon General.

(b) *Direct costs in general.* Funds granted for direct costs may be expended by the grantee for personal services, rental of space, materials, and supplies, and other items of necessary cost as are required to carry out the purposes of the grant. The Surgeon General may issue rules, instructions interpretations, or limitations supplementing the regulations of this subpart and prescribing the extent to which particular types of expenditures may be charged to grant funds.

(c) *Direct costs; personal services.* The costs of personal services are payable from grant funds substantially in proportion to the time or effort the individual devotes to carrying out the purpose of the grant. In such proportion, such costs may include all direct costs incident to such services, such as salary during vacations and retirement and workmen's compensation charges, in accordance with the policies and accounting practices consistently applied by the grantee to all its activities.

(d) *Direct costs; care of patients.* The cost of hospital, medical or other care of patients is payable from grant funds only to the extent that such care is incident to the research, training, or demonstration activities supported by a grant hereunder. Such care shall be incident to such activities only if reasonably associated with and required for the effective conduct of such activities, and no such care shall be charged to such funds unless the referral of the patient is documented with respect to the name of the practicing physician making the referral, the name of the patient, the date of referral, and any other relevant information which may be prescribed by the Surgeon General. Grant funds shall not be charged with the cost of—

(1) Care for intercurrent conditions (except of an emergency nature where the intercurrent conditions result from the care for which the patient was admitted for treatment) that unduly interrupt, postpone, or terminate the conduct of such activities.

(2) Inpatient care if other care which would equally effectively further the purposes of the grant could be provided at a smaller cost.

(3) Bed and board for inpatients in excess of the cost of semiprivate accommodations unless required for the effective conduct of such activities. For the purpose of this paragraph, "semiprivate accommodations" means two-bed, three-bed, and four-bed accommodations.

☐ 54.410 PAYMENTS.

The Surgeon General shall, from time to time, make payments to a grantee of all or a portion of any grant award,

to be incurred or incurred to the extent he determines such payments necessary to carry out the purposes of the grant.

☐ 54.411 DIFFERENT USE OR TRANSFER: GOOD CAUSE FOR OTHER USE.

(a) *Compliance by grantees.* If, at any time, the Surgeon General determines that the eligibility requirements for a program are no longer met, or that any facility or equipment the construction or procurement of which was charged to grant funds is, during its useful life, no longer being used for the purposes for which it was constructed or procured either by the grantee or any transferee, the Government shall have the right to recover its proportionate share of the value of the facility or equipment from either the grantee or the transferee or any institution that is using the facility or equipment. The Government's proportionate share shall be the amount bearing the same ratio to the then value of the facility or equipment, as determined by the Surgeon General, as the amount the Federal participation bore to the cost of construction or procurement.

(b) *Different use or transfer; notification.* The grantee shall promptly notify the Surgeon General in writing if at any time during its useful life the facility or equipment for construction or procurement of which grant funds were charged is no longer to be used for the purposes for which it was constructed or procured or is sold or otherwise transferred.

(c) *Forgiveness.* The Surgeon General may for good cause release the grantee or other owner from the requirement of continued eligibility or from the obligation of continued use of the facility or equipment for the grant purposes. In determining whether good cause exists, the Surgeon General shall take into consideration, among other factors, the extent to which—

(1) The facility or equipment will be devoted to research, training, demonstrations, or other activities related to Title IX diseases.

(2) The circumstances calling for a change in the use of the facility were not known, or with reasonable diligence could not have been known to the applicant, at the time of the application, and are circumstances reasonably beyond the control of the applicant or other owner.

(3) There are reasonable assurances that other facilities not previously utilized for Title IX purposes will be so utilized and are substantially the equivalent in nature and extent for such purposes.

☐ 54.412 PUBLICATIONS.

Grantees may publish materials relating to their regional medical program without prior review provided that such publications carry a footnote acknowledging assistance from the Public Health Service, and indicating that findings and conclusions do not represent the views of the Service.

☐ 54.413 COPYRIGHTS.

Where the grant-supported activity results in copyrightable material, the author is free to copyright, but the Public Health Service reserves a royalty-free, nonexclusive, irrevocable license for use of such material.

☐ 54.414 INTEREST.

Interest or other income earned on payments under this subpart shall be paid to the United States as such interest is received by the grantee.

APPENDIX 3

SUGGESTED AFFILIATION AGREEMENT FOR COOPERATION IN A REGIONAL MEDICAL PROGRAM

For the purpose of accepting Regional Medical Program funds and for the further purpose of voluntarily acknowledging the required fiscal responsibility,

the Regional Medical Program grantee,

and

the affiliating institution (or agency), in full recognition of the necessity for the affiliate to expend Federal monies received by the grantee under Title IX of the Public Health Act, as amended, and to assist the grantee in meeting its responsibilities under the terms of the grant, do enter into this agreement in support of the provisions of Sections 903 (b) and 904 (b) of the Act (copy of Title IX should be attached to this agreement).

Further, as a basis of assuring appropriate fiscal accountability in the expenditure of Regional Medical Program

grant funds, the above institutions (or agencies) do hereby execute this Agreement of Affiliation. And the affiliating institution does hereby give its assurances that it will administer, expend and be accountable for Regional Medical Program grant funds in accordance with the Act and in accordance with the current and future regulations and policies as may be outlined in the Guidelines of the grantor.

Accordingly, the above is mutually agreed by the parties to this affiliation agreement as witnessed by the signatures of their responsible officials.

Regional Medical Program Grantee

Affiliate

Responsible Official

Responsible Official

Title

Title

Date _____ 19 _____

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